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EXAMINER

TRAVERS, RUSSELL S

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/089,819

**Applicant(s)**

HUGHES ET AL.

**Examiner**

Russell Travers, J.D., Ph.D

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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Claims 1-18 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,

- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines those situations where "chronic pain" would be "prevented". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain those therapeutic regimens employed to effect diseases prevention without undue experimentation. In the instant case, only a limited number of individual situations are disclosed, or envisioned. Examiner notes prevention reads on the absolute relief of disease, and, or, symptomology: a situation rarely seen within the confines of medical practice. In the instant case, provided working examples fail to illustrate even one situation where any one of many envisioned "chronic pain" situations are prevented, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the therapeutic regimens required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on preventing all "chronic pain", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-9 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

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Claims 1-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 are rendered indefinite by the phrase "preventing...chronic pain" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Examples of what therapeutic goals would be encompassed in "preventing... chronic pain" are not set forth in the specification. Absent such exemplification, the skilled artisan could not establish the identity of those therapeutic situations that were envisioned as encompassed by regimens directed to "preventing...chronic pain". Applicant's phrase fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

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The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines structural features guiding the skilled artisan to those "NK<sub>1</sub> receptor antagonist" compounds, or "GABA analog" compounds envisioned as useful for practicing the invention as claimed. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of compounds are recited, absent a recitation of structural features to guide the skilled artisan to those "NK<sub>1</sub> receptor antagonist" compounds, or "GABA analog" compounds envisioned, thereby failing to provide sufficient working examples. It is noted that these

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examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all those "NK<sub>1</sub> receptor antagonist" compounds, or "GABA analog" compounds envisioned as useful for practicing the invention as claimed, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-9 and 18 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-6, 9-15 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6, 9-15 and 18 are rendered indefinite by the phrases "NK<sub>1</sub> receptor antagonist" and "GABA analog" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that are "NK<sub>1</sub> receptor antagonist" compounds, or "GABA analog" compounds are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Examiner notes the instant claims encompass all compounds possessing the function herein envisioned, discovered, and undiscovered. Applicants' failure to set forth the criteria integral to those compounds useful for practicing the claimed invention fails to establish the instant inventions metes and bounds. Applicant's term fails to

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clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

Claim 18 provides for the use of composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 18 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Horwell et al and Bryans et al.

Horwell et al (see column 2, line 6, column 8, lines 12-14 and Example 66) and Bryans et al teach the claimed instant NK<sub>1</sub> antagonist compounds, and GABA analog compounds respectively as old and well known in individually as useful for treating pain. These medicaments are taught as useful for treating chronic pain, and pain collateral to maladies seen as chronic: arthritis, neuropathic pain (see claims 42-43). Claims 1-18, and the primary references, differ as to:

- 1) the concomitant employment of these medicaments, and
- 2) administration levels of the medicaments.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional analgesic agents. It would follow that the recited claims define

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prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claims 2-3 and 11-12, specifically requires a pharmaceutical composition containing the individual ingredients in specific ratios. Horwell et al and Bryans et al employed the claimed compounds individually, not specifically reciting the concomitant employment. The skilled artisan would have seen conventional compositions useful for treating pain, and the therapeutic administration of these compositions to treat pain by conventional means as residing in the skilled artisan purview. Examiner additionally notes; "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" *In re Peterson*, 315 F.3d 1325 (CAFC 1003).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D., Ph.D whose telephone number is 571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'RS', enclosed within a large, loopy oval stroke.

**Russell Travers, J.D, Ph.D.**  
**Primary Examiner**  
**Art Unit 1617**